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**REMARKS/ARGUMENTS****Status of the claims:**

Claims 37-49 and 65 have been rejected. Claims 50-64 and 66-86 have been withdrawn from consideration due to Restriction Requirement and have been canceled without prejudice or disclaimer. Claims 1-36, 38-42, and 48-49 have also been canceled without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of the canceled subject matter in a continuation or divisional application. Claims 37, 43, and 65 have been amended.

Claims 37, 43-47 and 65 are pending.

**Amendments to the Specification**

The specification has been amended to state that the J53-C13 cell line of the present invention was deposited with the Patent Depository of the American Type Culture Collection (ATCC) and that the deposit will be maintained under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. The cells deposited with the ATCC (the "J53-C13 cell line" also referred to as "J53BL") are discussed throughout the specification. See, for example, page 17-19 of the specification. Methods of obtaining and using the J53-C13 cell line were also described in the application as filed. See, for example, page 16-17, that provides the method by which the J53-C13 cell line was obtained. Methods of using the J53-C13 cell line are provided on page 17 and 18, Example 3 and Example 4 (pages 18 and 19) of the specification. Accordingly, the addition of information designating the depository, accession number, and deposit date of the deposited cell line in the ATCC does not violate the prohibition of new matter in 35 U.S.C. 132. See, MPEP 2406.01.

The J53-C13 cell has been forwarded to the American Tissue Type Culture Collection. Upon receipt of the Official Patent Deposit Number from the ATCC, Applicants will provide a declaration under 37 C.F.R. §1.802 and enter the Patent Deposit Number into the blanks appearing in the specification and the claims.

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Amendments to the claims

Claims 37, 43, and 65 have been amended to recite a specific cell deposited with the ATCC. As outlined above, no new matter has been entered by way of this amendment.

Claim 43 has been further amended to recite "contacting said cell with a composition; and, assaying for marker gene expression to thereby determine if an HIV virus is present in said composition." Support for this amendment can be found, for example, on page 4, lines 7-24 and in Example 3, pages 16 and 17 of the specification.

The Rejection of the Claims Under 35 U.S.C. §112, Second Paragraph, Should Be Withdrawn

Claims 38 and 43-49 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite. This rejection is respectfully traversed.

Claim 38 was rejected for the term "originates from HeLa". As made of record in the Amendment and Response filed January 13, 2003, one of skill would be able to ascertain the scope of this claim. However, to expedite prosecution, claim 38 has been canceled.

Claim 43 and its respective dependant claims 44, 45, 46, and 47 were rejected as being unclear for reciting "a composition comprising at least one HIV virus". Claim 43 has been amended to recite "contacting said cell with a composition; and, assaying for marker gene expression to thereby determine if an HIV virus is present in said composition." As amended, claim 43 is clear and satisfies the requirements of 35 U.S.C. §112, second paragraph. The Examiner is respectfully requested to withdraw the rejection of claims 43-47.

The Rejection of the Claims Under 35 U.S.C. §112, First Paragraph, Should Be Withdrawn

Claims 43-49 were rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. This rejection is respectfully traversed.

The Examiner maintains that the recitation of "at least one HIV virus" renders the claim non-enabled. Applicants continue to maintain for the reasons of record that the claims are enabled. However, to expedite prosecution, claim 43 has been amended to recite "contacting said cell with a composition; and, assaying for marker gene expression to thereby determine if an

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HIV virus is present in said composition." As amended, claim 43 satisfies the requirements of 35 U.S.C. §112, first paragraph, and the Examiner is respectfully requested to withdraw the rejection of claims 43-47.

The Rejection of the Claims Under 35 U.S.C. §103 Should Be Withdrawn

Claims 37-49 and 65 were rejected under 35 U.S.C. §103 (a) as being rendered obvious in view of U.S. Patent No. 6,258,527 and Chackerian *et al.* (1997) *Journal of Virology* 71:3932-3939. This rejection is respectfully traversed.

Applicants would like to clarify on the record the teachings of Chackerian *et al.* Chackerian *et al.* teaches a MAGI CCR-5 cell line. See, Table 4, last column. This cell line comprises a CXCR4 receptor, a CD4 receptor, a CCR5 receptor and further contains a  $\beta$ -gal reporter gene under the control of the LTR promoter. See, page 3933, column 1, 3<sup>rd</sup> paragraph.

Applicants continue to maintain a *prima facie* case of obviousness has not been established. Claim 37, 43-47 and 65 and have been amended to recite a specific cell line deposited with the American Tissue Type Culture Collection. The deposited cell line (J53-C13) comprises two markers that can be used to detect HIV. See, page 14, Example 2 of the specification, and also, Figure 5 which demonstrates the detection of HIV using both markers. In this example,  $\beta$ -gal (infectious units) is plotted on the X-axis and luciferase activity is plotted on the Y-axis. As discussed above, Chackerian *et al.* discloses a cell line containing only a single marker for the detection of HIV. See, page 3933, column 1, first paragraph in Materials and Methods. U.S. Patent No. 6,258,527 also does not suggest the presence of two selectable markers. See, column 5, lines 5-20.

"The mere fact that a reference can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990). Neither Chackerian *et al.* nor U.S. Patent No. 6,258,527 suggest the presence of two markers in the cell that are capable of detecting HIV. Accordingly, as the prior art does not suggest the cells recited in claims 37 and 43-47 and 65 a *prima facie* case of obviousness has not been established and the Examiner is respectfully requested to withdraw the rejection of claims 37, 43-47 and 65 under 35 U.S.C. §103.

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Applicant's would further like to clarify a statement made on page 8, paragraph 2 of the Office Action mailed March 26, 2003. The Examiner states "since PBMC's express these same co-receptors, it is determined that the cells expressing the same combination of receptors taught by U.S. Patent No. 6,258,527 and Chackerian *et al.* would possess the same susceptibility." The assertion that a cell must simply express the three co-receptors to detect HIV as sensitively as PBMC's is incorrect. The Examiner is reminded that genomic position of transgene insertion, the promoters employed, along with other variables will impact the level of expression and possibly even the location of the expressed polypeptide in the cell. Therefore, the susceptibility of cell lines to HIV infection is unknown until the cell line is expressly tested for sensitivity to HIV infection.

#### CONCLUSIONS

In view of the foregoing amendments and remarks, Applicants respectfully submit that the rejection of claims 37, 43-47 and 65 are overcome. Accordingly, Applicants submit that this application is in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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## CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the Mail Stop AF, Commissioner for Patents, US Patent and Trademark Office at Fax No. 703-872-9307 on the date shown below.

*Pamela Lockley*  
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9/25/03

Date

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